IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of **Halseth**

Application No. 09/633,793

Attorney Docket No. 1032-P01510US1

Filed: August 7, 2000

For: Fluid Sampling Device with Retractable Needle

Examiner: Ghafoorian

Group Art Unit: 3731

RESPONSE TO FINAL ACTION

In an Official Action dated February 13, 2003, the Examiner indicated that Applicants constructively elected a species and that claims 16-58 were not directed to the constructively elected species. Accordingly, the Examiner withdrew claims 16-58 and did not examine the claims. Additionally, claims 1-4 and 14-15 were rejected under §102 over Allard 4,838,869, Garvin 5,984,898, Botich 6,179,812, Botich 6,123,688, Shaw 6,090,077, Shaw 6,015,438 and Caizza 6,036,674. Dependent claims 5-7 were rejected under §103 over these same references.

As discussed further below, Applicants request that the Examiner reconsider the withdrawal of claims 16-58, withdraw the finality of the previous official action, and examine claims 16-58. In addition Applicants request that the Examiner reconsider the rejection of claims 1-7 and 14-15 as discussed further below.

Claims 16-58 are Directed to the Species Claimed in the Originally Elected Claims

The Examiner contends that claims 16-58 are directed to a species that is

independent or distinct from the invention originally claimed in claims 1-7, and therefore, claims 16-58 were withdrawn from consideration without any examination on the merits. However, all of the inventions claimed in claims 16-58 are the same species as those covered by original claims 1-7.

The application originally included 13 claims. Claims 1-7 were method claims and claims 8-13 apparatus claims. The Examiner originally imposed a restriction requirement and Applicants elected the method claims of claims 1-7. The method claims as originally filed and examined in the first substantive action covered the following embodiments:

claim 1 was generic to all of the embodiments in Figures 1-13b;
claim 2 was generic to all of the embodiments in Figures 1-13b;
claim 3 was generic to all of the embodiments in Figures 1-13b;
claim 4 was is generic to all of the embodiments in Figures 1-11;
claim 5 was generic to all of the embodiments in Figures 1-13b;
claim 6 was generic to all of the embodiments in Figures 1-13b;
claim 7 was generic to all of the embodiments in Figures 1-13b.

Since the originally filed and examined claims were generic to all of the embodiments, there could be no constructive election. Accordingly, Applicants request that the Examiner reconsider the withdrawal of claims 16-58. Additionally, since the last official action was a final action and claims 16-58 were not examined substantively, Applicants request that the Examiner withdraw the finality of the last official action and examine claims 16-58.

Claims 1-7 and 14-15 are Patentable Over Allard 4,838,869

The Examiner did not provide any analysis of how the claim are anticipated by Allard. However, Allard is directed to a hypodermic syringe that is not capable of being used in accordance with the method of claims 1-4 and 14-15 as discussed further below.

Allard is a retractable needle hypodermic syringe. After an injection, the needle is automatically retracted into the plunger so that the needle is safe and the syringe cannot be used again. The syringe includes a plunger having a diaphragm 21 covering the forward end to provide a fluid seal. During use, medicine is drawn into the syringe barrel by pulling rearwardly on the plunger as with a standard syringe. The plunger is then driven forward to inject the medicine into the patient. As the plunger approaches the forward end of the barrel, the front end of the plunger breaks tabs 10 that hold the needle in place against the bias of a spring 16. The spring then propels the needle through the diaphragm 21. Since the diaphragm is pierced, the plunger can no longer draw a vacuum to draw fluid into the barrel or provide pressure to expel fluid from the barrel. Of course, that is because the Allard syringe is a non-reuseable injection device.

In short, Allard's syringe cannot be used to expel fluid from the barrel after the needle is retracted because the retracted needle pierces the diaphragm that provides a fluid seal. Since Allard cannot expel fluid from the syringe after the needle is retracted, Allard does not teach or suggest the step of expelling fluid after the needle is retracted, as recited in claim 1. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 1 and dependent claims 2-7 and 14-15 over Allard.

Furthermore, claim 4 recites the step of displacing the needle rearwardly into the housing while the collected fluid is in the housing. As discussed above, needle retraction is actuated by driving the plunger forwardly to expel the fluid from the barrel. At the end of the injection stroke, the plunger engages the tabs 10 to release the needle. Therefore, there is no way that the Allard device teaches or suggest the step of retracting the needle while the collected fluid is in the housing. Such a method would be contrary to the way that Allard operates. Accordingly, claim 4 is not obvious over Allard.

Claims 1-7 and 14-15 are Patentable Over Garvin 5,984,898

The analysis of Garvin is similar to the analysis of Allard. Specifically, Garvin teaches a single use hypodermic syringe. At the end of an injection stroke, the needle is released and retracted into the plunger. During the process of releasing the needle, a collapsible seal 44 on the end of the plunger 40 is broken so that the needle can be retracted into the plunger (see Fig. 3). By breaking the seal on the end of the plunger, the plunger is no longer operable to draw fluid into the barrel or expel fluid from the barrel.

In contrast to the injection device of Garvin, Applicants device is directed to a method for withdrawing a fluid sample. The method includes the step of collecting a fluid sample in a housing, retracting the needle and then expelling the collected fluid. Garvin does not teach or suggest these steps because Garvin is a injection device that necessarily retracts the needle after the fluid is expelled from the housing. Otherwise, it would not work as an injection device.

Accordingly, claim 1 and dependent claims 2-7 and 14-5 are patentable over Garvin. Further, dependent claim 4 recites the step of displacing the needle rearwardly while the collected fluid is in the housing. As in Allard, Garvin operates by pushing the plunger forward to inject medicine into a patient, and at the end of the injection stroke, the collapsible seal 44 is broken and the needle is retracted. Therefore, it would not be possible to retract the needle while the collected fluid is in the barrel. For this additional reason. claim 5 is patentable over Garvin.

Claims 1-7 and 14-15 are Patentable Over Botich 6,179, 812

The official action cites Botich '812 but does not provide any comparison of the patent to the pending claims. Instead, the official action includes a few sentences about Gibbs, which was not cited in the present official action. It appears that the

sentences were leftover from the previous official action. Accordingly, if the Examiner continues the rejection over Botich '812, Applicants request that the Examiner provide some analysis of how the Botich '812 patent applies to the pending claims.

Although the Examiner has not provided any analysis of how Botich '812 applies, Applicants will attempt to address what the Applicants believe the Examiner may have intended in the rejection. In the event that the Examiner continues the rejection over Botich '812, Applicants request that the Examiner provide an analysis of how Botich '812 applies to the claims.

Botich '812 discloses three types of devices, a syringe (Figs. 1-6), a phlebotomy device (Figs. 7-8) and a catheter insertion device (Figs. 9-13). The syringe is a retractable syringe for providing an injection, and it does not teach or suggest the method of claims 1-7 and 14-15 for similar reasons that Allard and Garvin do not teach or suggest the method. The catheter in Botich '812 clearly does not teach the step of the claimed method because the catheter does not teach or suggest collecting fluid. Accordingly, Applicants assume that the Examiner was basing the rejection on the phlebotomy device in Figs. 7 and 8, which is addressed below.

The phlebotomy device 320 in Botich '812 includes a barrel 322 having an open rearward end 322a for receiving a blood collection container 381, such as a "VACUTAINER", which is a glass tube with a seal at its forward end. The device includes a forward needle 325 for piercing the patient and a rearward needle 384 for piercing the seal on the collection container 381. When using the device, the collection container is evacuated so that blood can readily flow into the container. In addition, there is no plunger for expelling the fluid from the collection container.

Turning to the claims, the Botich '812 phlebotomy device does not include a plunger for expelling fluid from the housing. Further, the phlebotomy device does not

collect fluid in the housing. The fluid is collected in a container. Further still, the fluid is not expelled from the housing; it is expelled from the container. In light of all of these differences, Botich '812 does not teach or suggest the method of claim 1 and dependent claims 2-7 and 14-15. Accordingly, Applicants request that the Examiner reconsider the rejection of claims 1-7 and 14-15.

Claims 1-7 and 14-15 are Patentable Over Botich 6,123,688

Similar to the Botich '812 patent, the Examiner did not provide any analysis of how the Botich '688 patent applies to the pending claims. Further still, Botich '688 is directed to a number of retractable needle injectors for injecting medicine from a pre-filled vial of medicine. Therefore, Applicants cannot see how Botich '688 could teach or suggest the steps of collecting fluid. Particularly, Applicants do not see how Botich '688 could teach or suggest the step of expelling collected fluid after the needle is retracted, as recited in claim 1. The injectors could not provide an injection after the needle is retracted. Accordingly, claim 1 and dependent claims 2-7 and 14-15 are patentable over Botich '688.

Claims 1-7 and 14-15 are Patentable Over Shaw 6,090,077

Similar to the Botich '812 patent, the Examiner did not provide any analysis of how the Shaw '077 patent applies to the pending claims. Accordingly, if the Examiner continues the rejection over Shaw '077 Applicants request that the Examiner provide an analysis of how Shaw '077 applies to the steps in Applicants' claimed method.

Shaw '077 is directed to a retractable needle hypodermic syringe for giving injections similar to Allard and Gavin discussed above. Shaw '077 works similar to Allard and Gavin in that the needle is automatically retracted after the fluid is expelled from the syringe. In contrast, the claimed method includes the step of expelling the fluid after the needle is retracted. Again, during retraction, the Shaw '077

device breaks a seal at the end of the plunger so that the needle can be retracted into the plunger. Therefore, the plunger cannot be used to expel fluid from the barrel after retraction. Of course, that is because the Shaw '077 device is an injection device, not a collection device. Accordingly, there is no teaching or suggestion of the method recited in claims 1 and dependent claims 2-7 and 14-15.

Claims 1-7 and 14-15 are Patentable Over Shaw 6,015,438

Similar to the Shaw '077 patent, the Examiner did not provide any analysis of how the Shaw '438 patent applies to the pending claims. Accordingly, if the Examiner continues the rejection over Shaw '438 Applicants request that the Examiner provide an analysis of how Shaw '438 applies to the steps in Applicants' claimed method.

In addition, Shaw '438 is directed to a retractable needle hypodermic syringe for giving an injection. Shaw '438 operates similarly to the safety syringe disclosed in Shaw '077, which is discussed above. Accordingly, for reasons similar to those discussed above, claim 1 and dependent claims 2-7 and 14-15 are patentable over Shaw '438.

Claims 1-7 and 14-15 are Patentable Over Caizza 6,036,674

Similar to the Botich '812 patent, the Examiner did not provide any analysis of how the Caizza '674 patent applies to the pending claims. Accordingly, if the Examiner continues the rejection over Caizza '674 Applicants request that the Examiner provide an analysis of how Caizza '674 applies to the steps in Applicants' claimed method.

Caizza '674 is yet another retractable needle hypodermic syringe for providing an injection. As such, similar to the above referenced Allard, Garvin, and Shaw references, Caizza '674 does not teach or suggest the features of claims 1-7 and

14-15. Specifically, Caizza includes a plunger having a seal that is broken at the end of an injection stroke in order to allow the needle to be retracted into the plunger. Since the plunger seal is broken after the injection, and the needle is then retracted, there is no way to expel fluid from the housing after the needle is retracted, as recited in claim 1. Accordingly, claim 1 and dependent claims 2-7 and 14-15 are patentable over Caizza '674.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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Patent Application No. 09/633,793

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Response and accompanying papers are transmitted by facsimile to (703) 872-9303 on **July 14, 2003**.

July 14, 2003
Date of Certificate

Christine Edinger
Christine Edinger

Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **TWO** months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

July 14, 2003
Date of Certificate

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